

From the INTERNATIONAL BUREAU

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**PCT**NOTIFICATION CONCERNING  
TRANSMITTAL OF COPY OF INTERNATIONAL  
PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER I OF THE PATENT COOPERATION  
TREATY)

(PCT Rule 44bis.1(c))

To:

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Date of mailing (day/month/year)

30 July 2009 (30.07.2009)

Applicant's or agent's file reference

5618P8597PCT

**IMPORTANT NOTICE**

International application No.

PCT/US2008/051505

International filing date (day/month/year)

18 January 2008 (18.01.2008)

Priority date (day/month/year)

18 January 2007 (18.01.2007)

Applicant

ABBOTT CARDIOVASCULAR SYSTEMS INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

DATE IN TO FOREIGN DOCKETING 8/10/09

DATE RECEIVED BY \_\_\_\_\_

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The International Bureau of WIPO  
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 5618P8597PCT	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/US2008/051505	International filing date (day/month/year) 18 January 2008 (18.01.2008)	Priority date (day/month/year) 18 January 2007 (18.01.2007)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ABBOTT CARDIOVASCULAR SYSTEMS INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Box No. I  | Basis of the report   |
| <input type="checkbox"/> Box No. II            | Priority  |
| <input type="checkbox"/> Box No. III           | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV            | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> Box No. VI | Certain documents cited   |
| <input type="checkbox"/> Box No. VII           | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII          | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Telephone No. +41 22 743 81 00 Form PCT/IB/373 (January 2004)	Date of issuance of this report 21 July 2009 (21.07.2009)
	Authorized Officer  Dorothee Mülhausen e-mail: pm1.pct@wipo.int

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2008/051505

International filing date (day/month/year)  
18.01.2008

Priority date (day/month/year)  
18.01.2007

International Patent Classification (IPC) or both national classification and IPC  
INV. A61L26/00

Applicant  
ABBOTT CARDIOVASCULAR SYSTEMS INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of  
this opinion

see form  
PCT/ISA/210

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2008/051505

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2008/051505

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	<u>5, 12, 21, 24, 29, 34, 43</u>
	No: Claims	<u>1-4, 6-11, 13-20, 22-23, 25-28, 30-33, 35-42</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-43</u>
Industrial applicability (IA)	Yes: Claims	
	No: Claims	

2. Citations and explanations

see separate sheet

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- ✓ D1: WO 2004/050013 A (UNIV CALIFORNIA [US]; LEE RANDALL J [US]; CHRISTMAN KAREN [US]; SIEVER) 17 June 2004 (2004-06-17)
- ✓ D2: WO 2004/091592 A (GUIDANT CORP V I [US]) 28 October 2004 (2004-10-28)
- ✓ D3: WO 2006/113407 A (ADVANCED CARDIOVASCULAR SYSTEM [US]; CLAUDE CHARLES [US]; KWOK CONNIE) 26 October 2006 (2006-10-26)
- ✓ D4: ZHENG SHU X ET AL: "In situ crosslinkable hyaluronan hydrogels for tissue engineering" BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, vol. 25, no. 7-8, 1 March 2004 (2004-03-01), pages 1339-1348, XP004475078 ISSN: 0142-9612

Claims 1-45 relate to a surgical treatment or to a composition containing a post-myocardial tissue.

The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

Claims 1, 8, 13- 17, 22, 25, 30 and 35-39 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempts to define the subject-matter in terms of the result to be achieved (see for example claim 1 "sufficient to cause attenuation of a rate of myocardial expansion"), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. These formulations will be disregarded in the following discussion.

D1 which discloses the injection of a fibrin glue scaffolding agent into regions of damaged myocardium is novelty-destroying for the subject-matter of claims 13-20 and

22 (Article 33(2) PCT).

D2 discloses the use of dual component systems which are combined at the infarct zone for the formation of structurally reinforcing gels (see D2, [0141]). D2 is novelty-destroying for the subject-matter of claims 13-20 and 22 (article 33(2) PCT).

D3 relates to a method of forming a bioscaffolding comprising delivering a) a first component comprising hyaluronan and an electrophile and b) a second component comprising an hydrogel component e.g. fibrinogen and a nucleophile and crosslinking the first component and the second component in the infarcted region of the heart. D3 is novelty-destroying for the subject-matter of claims 1-4, 6-11, 13-20, 22-23, 25-28, 30-33 and 35-42 (Article 33(2) PCT).

The remaining subject-matter (claims 5, 12, 21, 24, 29, 34 and 43), although novel, cannot be considered as being inventive for the following reasons:

D2 discloses the use of dual component systems for the formation of structurally reinforcing gels for application to the infarct region.

The subject matter of claims 5, 12, 21, 24, 29, 34 and 43 differs from the teaching of D2 which can be considered to represent the closest prior art in the composition of the first and second gelation systems used for forming a bioscaffolding. In the absence of any effect, the problem underlying the present invention may be seen as to provide alternative gelation systems.

The choice of the first and second two component systems is merely one of several straightforward possibilities from which the skilled person would select, all the more since D2 does not only disclose a dual system comprising sodium alginate as a first component and calcium chloride as a second component but also the possibility of combining these dual component systems with other systems utilizing fibrin. Thus the subject-matter of claims 5, 12, 21, 24, 29, 34 and 43 cannot be considered as being inventive (Article 33(3) PCT).

#### **Re Item VI**

#### **Certain documents cited**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2008/051505

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
✓ WO2007/145909	21/12/07	04/06/07	05/06/06*

WO2007/145909 appears to be particularly relevant.

\* No check has been made as to whether the priorities have been validly claimed.